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Abstract: STUDY DESIGN: Prospective, multicenter cohort study. **OBJECTIVE:** The aim of our study was to assess the course of patients over a period of three years undergoing surgical or non-surgical treatments for degenerative lumbar spinal stenoses (DLSS) based on data from the Lumbar Stenosis Outcome Study (LSOS), prospectively performed in eight hospitals. **SUMMARY OF BACKGROUND DATA:** The optimal treatment strategy for patients with DLSS is still debated. **METHODS:** The outcomes of patients with verified DLSS were quantified by Spinal Stenosis Measure (SSM) symptoms- and SSM function-scores, and EQ-5D-3L (quality of life) summary index (SI) over time (up to 36-month follow-up), and minimal clinically important difference (MCID) in SSM symptoms, SSM function, and EQ-5D-3L SI from baseline to 36-month follow-up. **RESULTS:** For this study, 601 patients met the inclusion criteria; 430 underwent surgery, 18 of them only after more than a year after enrolment, 171 received non-surgical treatment only. At baseline, patients in the surgical and nonsurgical groups had similar values for the SSM symptoms and SSM function scores, but patients in the surgical group suffered significantly more from buttocks pain and reported more worsening symptoms over the last three months before enrollment in the study. Surgically treated patients (except changers) performed significantly better in all clinical outcome measures ($p < 0.001$) with a plateau at 12-month follow-up staying constant until the follow-up ended. Further, two thirds of patients in the surgical group had a relevant improvement in function, symptoms, and quality of life, compared to only about half of those in terms of symptoms and even less in terms of function and quality of life with non-surgical treatment. **CONCLUSIONS:** Surgical treatment of DLSS results in more favorable clinical outcomes with a sustained effect over time, compared to non-surgical treatment. **LEVEL OF EVIDENCE:** 3

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Long-term results after surgical or non-surgical treatment in patients with degenerative lumbar spinal stenosis: a prospective multi-center study

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Abstract

Study Design. Prospective, multicenter cohort study.

Objective. The aim of our study was to assess the course of patients over a period of three years undergoing surgical or non-surgical treatments for degenerative lumbar spinal stenoses (DLSS) based on data from the Lumbar Stenosis Outcome Study (LSOS), prospectively performed in eight hospitals.

Summary of Background Data. The optimal treatment strategy for patients with DLSS is still debated.

Methods. The outcomes of patients with verified DLSS were quantified by Spinal Stenosis Measure (SSM) symptoms- and SSM function-scores, and EQ-5D-3L (quality of life) summary index (SI) over time (up to 36-month follow-up), and minimal clinically important difference (MCID) in SSM symptoms, SSM function, and EQ-5D-3L SI from baseline to 36-month follow-up.

Results. For this study, 601 patients met the inclusion criteria; 430 underwent surgery, 18 of them only after more than a year after enrolment, 171 received non-surgical treatment only. At baseline, patients in the surgical and nonsurgical groups had similar values for the SSM symptoms and SSM function scores, but patients in the surgical group suffered significantly more from buttocks pain and reported more worsening symptoms over the last three months before enrollment in the study. Surgically treated patients (except changers) performed significantly better in all clinical outcome measures ($p < 0.001$) with a plateau at 12-month follow-up staying constant until the follow-up ended. Further, two thirds of patients in the

surgical group had a relevant improvement in function, symptoms, and quality of life, compared to only about half of those in terms of symptoms and even less in terms of function and quality of life with non-surgical treatment.

Conclusions. Surgical treatment of DLSS results in more favorable clinical outcomes with a sustained effect over time, compared to non-surgical treatment.

Key Words: clinical meaningful improvement; decompression; degenerative lumbar spinal stenosis; Fusion; long-term; MCID; multi-center; non-surgical; Quality of life; SSM

Level of Evidence: 3

Key Points

- The optimal treatment strategy for patients with degenerative lumbar spinal stenoses is still debated.
- At baseline patients in the surgical and nonsurgical groups had similar values for the Spinal Stenosis Measure (SSM) symptoms and SSM function scores, but patients in the surgical group suffered significantly more from buttocks and/or leg pain, reported more worsening symptoms over the last three months before enrollment in the study, responded poorer to pain medications, and had more levels with concomitant degenerative spondylolisthesis.
- Two thirds of patients in the surgical group had a relevant improvement in function, symptoms, and quality of life after three years, compared to only about half of those in the non-surgical group in terms of symptoms and even less in terms of function and quality of life with non-surgical treatment.

Introduction

Degenerative lumbar spinal stenosis (DLSS) is a highly prevalent condition and causes considerable pain and disability.¹ The underlying somatic anomaly is narrowing of the lumbar spinal canal by bulging discs, hypertrophy of surrounding bone and overgrowth of soft tissues that compromise neural and vascular elements.² Patients typically complain of pain in the buttocks and lower extremities provoked by walking or extended standing and relieved by rest or bending forward.^{2,3}

The treatment options range from non-surgical approaches such as analgesics, physiotherapy, and epidural corticosteroid injections to surgical methods. In the last few decades, the number of surgical procedures to treat DLSS has worldwide increased steadily⁴⁻⁷ – in particular in patients older than 65 years of age⁸ – despite debates on mid- to long-term improvement in pain or disability⁹⁻¹¹ and a potential higher economic burden of surgery.⁴

Despite of an impressive number of published studies,^{9,11-23} the best treatment strategy for patients with DLSS is still a matter of debate. As stated by the authors of a Cochrane review²⁴ it appears to be uncertain whether surgical or non-surgical treatment leads to better results in patients with lumbar spinal stenosis. Evidence on the benefit of the non-surgical treatments is lacking or scarce, except for a short-term improvement of symptoms after epidural injections of steroids and analgesics.²⁵ After surgery about one third of the patients report no relevant improvement of symptoms and rates of reoperations range between 6% and 15% within two to five years^{11,22,26-28} after decompression-alone or after decompression and fusion surgery.^{26,29}

The aim of our study was to assess the course of patients over a period of three years undergoing surgical or non-surgical treatments for DLSS based on data from the Lumbar Stenosis Outcome Study (LSOS), a multicenter Swiss cohort study.

Material and Methods

Study design and inclusion criteria

This study was conducted in compliance with international laws and regulations as well as any applicable guidelines. The study was approved by the independent Ethics Committee of the Canton Zurich (KEK-ZH-NR: 2010-0395/0). Written informed consent to participate in the study has been obtained from participants.

The Lumbar Stenosis Outcome Study (LSOS) is a multicenter initiative, conducted as a prospective cohort study in the Rheumatology and Spine Surgery Units at eight medical centers (which service a region in Switzerland with approximately two million inhabitants) and includes data of 679 patients documented over a period of 3 years in a prospective manner.³⁰ Patients were included into this study if they were 50 years or older and had a diagnosis of DLSS verified by Magnetic Resonance Imaging (MRI) or Computer Tomography (CT) with symptoms of neurogenic claudication. Patients were excluded if the stenosis was caused by tumor, fracture, infection, or significant deformity ($>15^\circ$ lumbar scoliosis, diagnosed on conventional x-ray with anterior-posterior and lateral views) or with a history of previous spinal surgery. Further exclusion criterion was symptomatic peripheral artery occlusive disease.

Treatment

The choice of the treatment strategy (non-surgical or surgical) was made by the attending physician based on patients' symptoms and preferences. Non-surgical therapy consisted of analgesics, physiotherapy, and/or lumbar epidural/nerve root/facet joint injection (of steroids and/or analgesics).

Surgical patients underwent either decompression alone or decompression with instrumented fusion surgery. Decompression surgery consisted of a standard open or

microscopic posterior lumbar decompression (laminotomy) of the affected level(s). Decompression of the lateral recess and the foramina was performed when necessary to decompress the exiting nerve roots. Fusion surgery consisted of decompression surgery and pedicle screws instrumentation with or without intercorporeal cage(s) at the affected level(s). It was at the discretion of the surgeons to add fusion and to proceed with single- or multi-level procedures, based on patients' symptoms and MRI-findings.

Outcome Measures

The outcomes of our study were quantified by Spinal Stenosis Measure (SSM) symptoms and SSM function scores, and EQ-5D-3L (quality of life) summary index (SI) over time (measured at baseline, 12-, 24-, and 36-month follow-up), and minimal clinically important difference (MCID) in SSM symptoms, SSM function, and EQ-5D-3L SI from baseline to 36-month follow-up.

Spinal Stenosis Measure (SSM): The SSM is a self-administered validated three-part questionnaire that was specifically designed for DLSS patients to measure the severity of symptoms and disability.³¹ It is widely used in studies on DLSS^{23,32-34} and recommended by the North American Spine Society (NASS). It consists of three different subscales; *the symptom severity subscale, the physical function subscale* and the *satisfaction subscale*. The subscale score ranges are 1–5, 1–4 and 1–4 (best-worst). MCID for SSM symptoms is defined as an improvement (decrease) by at least 0.48 points, and for SSM function by at least 0.52 points.³⁵

EQ-5D-3L: The EuroQol five-dimensional questionnaire (EQ-5D) is a standardized instrument to measure health-related quality of life (HRQOL) and was developed by the EuroQol Group.³⁶ The first element, the EQ-5D descriptive system, measures the health state in five dimensions (mobility, self-care, usual activities, pain/discomfort, and

anxiety/depression), with three levels of severity for each dimension (EQ-5D-3L).³⁶ The five dimensions can be reported as a single 5-digit number (from 11111 representing full health to 33333, meaning worst health). With help of a value set (depending on population norms), the health state can be converted into a single summary index (SI) value. This value can range from -0.53 (for the French population) to 1, with 0 representing a health state equivalent to being dead and 1 indicating full health. MCID is defined as an improvement (increase) by at least 0.19 points [article submitted, under review]. The second element, the EQ-5D Visual Analogue Scale (VAS), measures the health status on a vertical scale between 0 and 100 (worst to best imaginable health state) on a particular day.

Morphological data based on MRI

Two senior radiologists assessed the MRI of each patient according to the consensus paper of Andreisek et al.³⁷ Three core parameters were used to verify and to describe the severity of lumbar spinal stenosis (**Appendix Table 1**): 1) compromise of the central zone,³⁸ 2) relation between fluid and cauda equina (Schizas classification),³⁹ and 3) nerve root compression in the lateral recesses.⁴⁰ Further parameters used were compromise of the foraminal zone³⁸ and foraminal nerve root impingement.⁴¹ The Meyerding classification was used to grade the severity of the spondylolisthesis.⁴²

Statistical analysis

Summary tables report count (percentage), mean (standard deviation) and median (interquartile range) as appropriate and with P-values from chi-squared, ANOVA or Kruskal-Wallis tests correspondingly. Non-parametric Kruskal-Wallis tests are used to test for differences in improvement between treatment groups and types of surgery in unadjusted

analyses and chi-squared tests to compare proportions of patients reaching MCID. Further investigation of the potential differences due to treatment and other risk factors is done with linear models for the outcomes at 36 months. The models include treatment group, baseline score of the respective outcome, age, sex, diabetes, low education, civil risk, BMI, smoker, pain duration, Hospital Anxiety and Depression Scale (HADS, depression subscore), coxarthrosis, gonarthrosis, Cumulative Illness Rating Scale (CIRS), buttocks pain, leg pain, disease progression, degenerative spondylolisthesis, and number of stenotic levels.

All analyses are conducted with R for Windows.⁴³

Results

Baseline patient characteristics

Between December 2010 and December 2015, 841 patients agreed to participate in the LSOS study (**Figure 1**). Of these, 114 patients had history of spinal surgery prior to baseline and 48 had no MRI examination, therefore they were excluded from this analysis. Of the remaining 679 patients, 436 (64.2%) underwent initial surgery during the first year (surgical group), 225 (33.1%) had non-surgical treatments only (non-surgical group), and 18 (2.7%) were first treated non-surgically and all underwent surgery after the first year of enrollment (changers group). Seventy-nine (11.6%) patients dropped out before 12-month follow-up (for reasons see **Appendix Table 2**).

Table 1 presents the patient characteristics at baseline for patients in each group who had at least 12-month follow-up ($n = 601$). Overall, patients who underwent surgery within the first year were slightly younger, had a lower civil risk, suffered significantly more from buttocks and/or leg pain, had less coxarthrosis or gonarthrosis, and reported more worsening symptoms over the last 3 months with a higher degree of dissatisfaction with their quality of life (EQ-5D-3L SI) at baseline.

Morphological findings on MRI

The morphological evaluation on MRI is shown in **Table 2**. The most stenotic levels (at least one moderate grading in one of the three core parameters) were L4/5 followed by L3/4. Most patients had moderate or severe stenoses on two or three levels. The surgically treated patients had significantly more levels with severe stenoses ($p < 0.001$) than the non-surgically treated with a higher level of compromise of the central zone ($p = 0.007$), lesser cerebral spinal fluid to cauda ratio ($p < 0.001$) and more compression in the lateral recession ($p = 0.022$) (**Table**

2). In addition, concomitant degenerative spondylolisthesis was more common on levels L4/L5 ($p=0.028$) and L3/L4 ($p=0.029$) in the surgical group.

Table 3 shows the proportion of operated levels for either moderate or severe stenotic levels in the surgical group. The rate of operation of severe stenotic levels was much higher compared to that of moderate stenotic levels (Odds ratio 14.2, 95% confidence interval 10.6 to 19.3). The number of levels that underwent surgical decompression were correlated with the MRI grading of number of severely stenotic levels (correlation $r = 0.88$, $p<0.001$, **Appendix Table 3**).

Non-surgical treatment

Of the non-surgically treated patients, almost all received physiotherapy and/or analgesics (**Table 4**). During the study period, 23.4% received one corticosteroid injection (epidural, nerve root, or facet joints) and 53.2% of the patients had two or more injections. In the surgical group, almost half of the patients (44.2%) did not receive any injections whereas in the changers group all patients received at least one injection before surgery (**Table 4**).

Surgical treatment types, surgical complications, and reoperations

In the surgical group, 320 (77.7%) of the patients underwent surgical decompression alone and 92 (22.3%) a decompression with fusion surgery (**Table 5**). The most common intraoperative complication was a dural tear (6.1%). In total, 63 reoperations in 51 (12.4%) patients were performed, in 36 (11.3%) patients after decompression-alone surgery and 15 (16.3%) patients after decompression and fusion surgery. Nine and three patients underwent two and three reoperations, respectively. The most common reason was a restenosis (73.0%) (**Table 5**).

The linear regression models of decompression alone surgery versus fusion surgery for SSM symptoms, SSM function, and EQ-5D-3L SI did not provide evidence that fusion surgery was associated with a more favorable clinical outcome (**Appendix Table 4a-c**).

Clinical outcomes of different treatment strategies (surgical vs. non-surgical)

Figure 2 depicts the overall course over time for the three treatment groups. At baseline the non-surgically treated patients did not differ significantly in regard to their SSM symptoms and SSM function scores and had only slightly higher scores for quality of life (EQ-5D-3L SI) compared to the patients in the surgical group. Over time however, surgically treated patients (except changers) performed significantly better in all clinical outcome measures (SSM symptoms, SSM function, and EQ-5D-3L SI; $p < 0.001$, unadjusted) with a plateau at 12-month follow-up staying constant until the follow-up end. The linear regression models for SSM symptoms, SSM function, and EQ-5D-3L SI confirmed that the surgically treated patients had better clinical outcomes at 36-month follow-up compared with the other two treatment groups (**Appendix Table 5a-c**). Overall, HADS and CIRS were negatively correlated with the here documented clinical outcome measures.

In the surgical group 245 (67.1%) patients reported an MCID for SSM function, 265 (72.6%) for SSM symptoms, and 224 (61.4%) for EQ-5D-3L SI. The corresponding numbers in the non-surgical group were 55 (37.4%), 76 (51.7%), and 45 (30.6%), and in the changers group 6 (35.3%), 9 (52.9%), and 5 (29.4%), respectively.

Discussion

Patients who underwent surgical treatment of DLSS reported significantly better clinical outcomes – less pain and overall better function and quality of life – compared to patients with non-surgical treatment after three years. Two thirds of patients in the surgical group had a clinically relevant improvement in function, symptoms, and quality of life, compared to only about half of those in the non-surgical group in terms of symptoms and even less in terms of function and quality of life. On the other hand, one in eight patients in the surgical group had to be revised after initial surgery, mainly due to restenosis. Further, three percent of the initially non-surgically treated patient needed surgery within the period of observation.

The optimal treatment strategy for patients with DLSS is still debated, in spite of a remarkable number of published studies.^{9,11-23} Although the authors of a recently published Cochrane review²⁴ concluded that it is still uncertain whether surgical or non-surgical treatment leads to better results in individual patients. Three randomized trials (RCTs)^{11,12,19} and two cohort studies^{14,16} provide evidence that surgery lead to better outcomes (up to five to six years) compared to non-surgical treatment. The results of our study are in agreement with those of these trials. In the SPORT study of Weinstein et al.¹¹ a total of 654 patients were enrolled. The authors reported that the surgically treated patients improved more in all primary outcome measures than the non-surgically treated patients at 4-year follow-up. After eight years, there was no benefit of surgery in the randomized group any more, but in the observational group the results remained in favor for surgery.⁴⁴ Malmivaara et al.¹⁹ concluded in their randomized study investigating a total of 94 patients that decompressive surgery yielded greater improvement than non-operative treatment at 2-year follow-up. After six years, there was a favorable difference in the Oswestry Disability Index (ODI) but not for leg or back pain.²¹ And in the RCT of Amundsen et al.¹² 100 patients were included and followed up to ten years with better clinical outcomes in the surgery group. In the cohort study of Atlas

et al.^{9,14} including 148 patients, surgical treatment resulted in greater improvement in patient-reported outcomes at 4-year follow-up, but after 8 to 10 years only leg pain and back-related functional status remained in favor for the surgical treatment group. Chang et al.¹⁶ reported in their cohort study with 144 patients that surgically treated patients benefitted more than non-surgically treated patients during the 10-year follow-up, but the positive effect diminished in the later years. Only the recently published RCT by Delitto et al.¹⁷ did not show a benefit for surgery compared to physiotherapy at 2-year follow-up. In short, surgical treatments – decompression techniques with and without fusion – seem to be more effective in regard to longer term improvement of symptoms but carry the disadvantages of potential early and late complications after surgery.⁴

The main limitations of this study are the lack of standardization of decision processes for different treatment strategies and the non-random allocation of patients to surgical or non-surgical treatment. To our knowledge there is no broadly accepted consensus on the indication for surgery or non-surgical treatment, except for a rapid deterioration of symptoms with neurological deficits. The decision for one of the treatment modalities was based on the judgement and recommendation of physicians and the preferences of patients. The unequal distribution of baseline characteristics between the surgical and non-surgical groups indicates that patients with more severe symptoms were operated. Patients in the surgical group suffered significantly more from buttocks and/or leg pain, reported more worsening symptoms over the last three months before enrollment in the study, responded poorer to pain medications, and had more levels with concomitant degenerative spondylolisthesis. This unequal distribution of baseline characteristics limits the comparison of treatment options; we believe the findings represent the reality of the clinical practice and decision making. We did not attempt to derive any causal treatment effect for surgical versus non-surgical therapy.

A second limitation is the non-random assignment of patients to one of the treatments. The aim of LSOS was not to prove the efficacy of surgery itself, compared to non-surgical treatment, but to observe a cohort of DLSS patient undergoing usual clinical care. It is important to note that the aforementioned RCTs^{11,12,17,19} had substantial difficulties with their adherence to protocol because not all patients received the assigned treatment and a remarkable proportion (43% to 57%)^{12,17,22} of patients who were allocated to non-surgical treatment did finally undergo surgery. We expect that in a future randomized trial there would be a similarly high change rate.

There are still many questions unanswered about the optimal treatment of patients with DLSS. Many patients with DLSS have stenoses on more than one level. These multisegmental stenoses in the MRI are a major challenge for the surgeons. So far, MRI findings seem not to be very helpful to tell the surgeon which level(s) is (are) causal for the symptoms. These circumstances make it difficult to decide which stenoses the surgeon needs to decompress. Our findings suggest, that such a decision is particularly challenging with moderately but not severely stenotic levels. A further question is which patients benefit from decompression with fusion.

With the above-mentioned limitations in mind, we conclude that surgical treatment of DLSS results in more favorable clinical outcomes with a sustained effect over time, compared to non-surgical treatment.

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Figure 1: Study flow



Figure 2: Overall course of all patients per treatment group over the study period

Legend 2: SI, summary index; SSM, Spinal Stenosis Measure

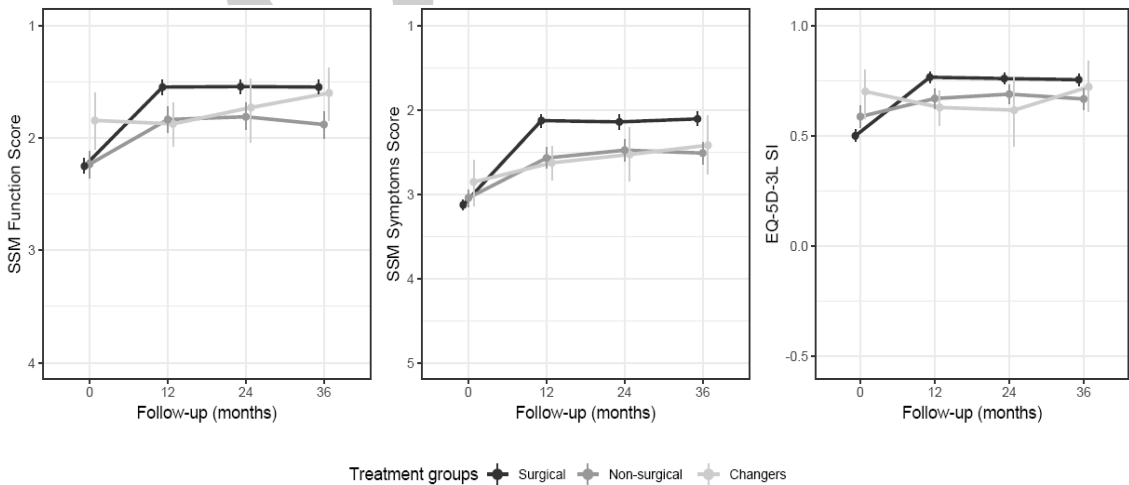


Table 1: Baseline patient characteristics

ACCEPTED

Table 2: Radiologic evaluations of the MRIs

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Table 3: Proportion of operated levels for either moderate or severe stenotic levels in the surgical group

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Table 5: Surgical treatments, surgical complications, and reoperations

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